CV 23 - 9073

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

TOTAL BODY NUTRITION LLC and TBN Labs LLC, New York corporations, and LOUD MUSCLE SCIENCE, LLC, a Delaware corporation,

and

MOHAMMED ISLAM, individual,

Defendants.

COMPLAINT FOR PERMANENT INJUNCTION

Civil No. _____

BROWN, J.

SHIELDS, M.J.

COMPLAINT

The United States of America ("Plaintiff"), by its undersigned counsel, acting on behalf of the United States Food and Drug Administration ("FDA"), brings this civil action under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act"), 21 U.S.C. §§ 301 *et seq.*, seeking permanent injunctive relief to prevent the Defendants from continuing to violate federal dietary supplement safety laws. In support of this Complaint, Plaintiff alleges as follows:

PARTIES

1. Plaintiff is the United States of America.

2. Defendants Total Body Nutrition LLC and TBN Labs LLC are New York companies, and Loud Muscle Science, LLC, is a Delaware company (collectively, "TBN"),

located at 300 Oser Avenue, Hauppauge, New York 11788 ("the Facility"), within the Eastern District of New York.

3. TBN is a contract-manufacturer of dietary supplements and was previously a manufacturer and distributor of own-label dietary supplements.

4. Defendants receive raw materials from out-of-state contract manufacturers, including sources in New Jersey and China, to manufacture dietary supplements. Defendants sell their finished products to distributors in New York and to customers in various states, including Texas, Ohio, New Jersey, and California.

5. TBN maintains www.TBNLabs.com, which is registered to Defendant Mohammed Islam. TBN also owns and controls other websites, including www.intim8science.com and www.wedoprivatelabel.com. Defendants also sell their products on Amazon and eBay under the username tbnlabs.

6. Defendant Mohammed Islam is TBN's owner and Chief Executive Officer. He is the most responsible person at TBN and handles all aspects of the business, including but not limited to, all major purchases and financial decisions, product formulations, customer relations, new product development, sales through trade shows, and website maintenance, and he has the authority to hire and fire employees. Mr. Islam performs his duties at the Facility, within the Eastern District of New York.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

8. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. §§ 1391(b) and (c).

STATUTORY AND REGULATORY FRAMEWORK

9. Congress enacted the Dietary Supplement Health and Education Act of 1994 as an amendment to the FDCA "to establish standards with respect to dietary supplements." Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. §§ 301-399f).

10. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). A dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." *Id.*

11. The Act requires dietary supplement manufacturers to operate in compliance with the current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP regulations") set forth in 21 C.F.R. Part 111. 21 U.S.C. § 342(g)(1). To comply with the Dietary Supplement CGMP regulations, manufacturers must incorporate a set of controls in the design and production stages of the manufacturing process to ensure a finished product of acceptable, predictable, and reliable quality. Dietary supplements not prepared, packed, or held in conformance with the Dietary Supplement CGMP regulations are deemed to be adulterated. 21 U.S.C. § 342(g)(1).

12. The Dietary Supplement CGMP regulations are designed to ensure the quality of dietary supplements. These regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements. These regulations require such persons to control all aspects of their processes and procedures to ensure

compliance with established specifications for identity, purity, strength, composition, and limits on certain types of contamination.

13. The Act deems a dietary supplement to be misbranded if its label fails to provide the common or usual name of individual ingredients; its labeling fails to state the name of any artificial coloring contained in the product; its label or labeling fails to present the nutrition information in a Supplement Facts panel; its label or labeling fails to identify the part of the plant from which each botanical dietary ingredient is derived; or its label fails to include a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with the dietary supplement. 21 U.S.C. §§ 343(i)(2), (k), (q)(5)(F), (s)(2)(C), and (y).

DEFENDANTS' VIOLATIONS OF THE ACT

14. Many of Defendants' products fall within the Act's definition of a dietary supplement because they are not represented for use as a conventional food or as a sole item of a meal, they each contain at least one ingredient that is a "dietary ingredient" as defined in 21 U.S.C. § 321(ff), and they are labeled as dietary supplements.

15. Defendants have a history of violating the Act, as observed by FDA during four separate inspections conducted between 2017 and 2023. At the close of each inspection, FDA investigators issued a List of Inspectional Observations, Form FDA 483 ("Form 483"), to Defendants Islam and TBN and discussed each of the observed violations of the Dietary Supplement CGMP regulations with Defendant Islam. FDA also sent three Warning Letters to Defendants Islam and TBN.

16. On March 31, 2016, FDA issued a Warning Letter to Defendants Islam and TBN, informing them that they were introducing misbranded dietary supplements into interstate

commerce; specifically, their Ephedra Free Tummy Tuck and Ephedra Free Shredder products were misbranded because their labels improperly declared methylsynephrine as a dietary ingredient.

17. FDA inspected Defendants' previous manufacturing facility, which was located at 100 Executive Drive, Edgewood, New York, 11717, between February 3 and March 31, 2017 ("2017 Inspection"). During the 2017 Inspection, FDA investigators observed multiple violations of the Dietary Supplement CGMP regulations. These violations included, but were not limited to: failure to verify that finished batches of dietary supplements met product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or lead to adulteration of the finished batches of dietary supplement, and failure to establish an adequate batch production record that included all required elements.

18. On September 28, 2017, FDA issued a Warning Letter to Defendants Islam and TBN, informing them that they were introducing into interstate commerce adulterated and misbranded dietary supplements, and describing specific examples of violations of the Dietary Supplement CGMP regulations and ways in which TBN had misbranded some of its dietary supplements. The Warning Letter also informed them that they were introducing into interstate commerce unapproved new drugs and misbranded drugs (Omega-3-Fish Oil and Total Estro), based on claims made on their product labels and website and the failure to include adequate directions for the product's safe use.

19. FDA inspected Defendants' previous manufacturing facility between May 9 and June 22, 2018 ("2018 Inspection"). During the 2018 Inspection, FDA investigators observed multiple violations of the Dietary Supplement CGMP regulations. These violations included, but were not limited to: failure to verify that finished batches of dietary supplements met product

specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or lead to adulteration of the finished batches of dietary supplement, and failure to establish an adequate batch production record that included all required elements.

20. On April 11, 2019, FDA issued a Warning Letter to Defendants Islam and TBN, informing them that they were introducing into interstate commerce adulterated dietary supplements in addition to other violations.

21. FDA inspected Defendants' previous manufacturing facility between February 16 and March 3, 2021 ("2021 Inspection"). During the 2021 Inspection, FDA investigators observed multiple violations of the Dietary Supplement CGMP regulations. These violations included, but were not limited to: failure to establish product specifications for the identity, purity, strength, and composition of each finished batch of dietary supplement, and failure to verify that finished batches met product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or lead to adulteration of the finished batches of dietary supplement, and failure to verify the identity of a dietary ingredient prior to its use.

22. After the 2021 Inspection, Defendants moved their manufacturing business to the Facility where it now operates. FDA inspected the Facility between February 21 and March 23, 2023 ("2023 Inspection"). During the 2023 Inspection, FDA investigators observed multiple violations of the Dietary Supplement CGMP regulations that were identical to, or similar to, CGMP deviations observed during FDA's 2021 Inspection. These violations included, but were not limited to: failure to establish product specifications for the identity, purity, strength, and composition of each finished batch of dietary supplement, and failure to verify that finished

batches met product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or lead to adulteration of the finished batches of dietary supplement.

23. In response to FDA's communications, Defendant Islam has repeatedly promised to take corrective action and has submitted reports of his actions to FDA. But, as evidenced above, FDA has observed many of the same violations of the Dietary Supplement CGMP regulations during multiple inspections of TBN.

24. Plaintiff now seeks the Court's assistance with enforcing the FDCA against Defendants because, based on the Defendants' continuing violations, it has become clear that unless enjoined, restrained, and prohibited from further violations, Defendants will continue to violate the FDCA.

CLAIMS FOR RELIEF

COUNT I

Dietary Supplements Caused To Be Adulterated

25. Plaintiff realleges and incorporates by reference all preceding paragraphs.

26. On various dates in February and March 2017, May and June 2018, February and March 2021, and February and March 2023, Defendants violated the FDCA, 21 U.S.C. § 331(a), by manufacturing dietary supplements not prepared, packed, or held in conformance with the Dietary Supplement CGMP regulations, as required by 21 U.S.C. § 342(g)(1), and introducing or delivering for introduction into interstate commerce such adulterated dietary supplements.

27. On various dates in February and March 2017, May and June 2018, February and March 2021, and February and March 2023, Defendants also violated 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1),

because they had been prepared, packed, or held under conditions that did not meet the Dietary Supplement CGMP regulations, 21 C.F.R. Part 111, while such articles were held for sale after shipment of one or more of their components in interstate commerce.

COUNT II

Dietary Supplements Caused To Be Misbranded

28. Plaintiff realleges and incorporates by reference all preceding paragraphs.

29. On various dates between 2016 and the present, Defendants violated the FDCA, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce dietary supplements that were misbranded, pursuant to 21 U.S.C. § 343(i)(2), (k), (q)(5)(F), (s)(2)(C), and/or (y).

30. On various dates between 2016 and the present, Defendants violated the FDCA, 21 U.S.C. § 331(k), by causing dietary supplements to become misbranded within the meaning of 21 U.S.C. §§ 343(i)(2), (k), (q)(5)(F), (s)(2)(C), and/or (y), while such articles were held for sale after shipment of one or more of their components in interstate commerce.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that judgment be entered in its favor and against the Defendants, and seeks entry of an order granting the following relief:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343; and

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce.

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the receipt, manufacture, preparation, processing, packing, repacking, labeling, holding, and/or distribution of all of Defendants' dietary supplements, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

III. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this ____ day of _____, 2023.

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director
Consumer Protection Branch

KIMBERLY STEPHENS Digitally signed by KIMBERLY STEPHENS Date: 2023.12.08 11:31:27 -05'00'

KIMBERLY R. STEPHENS
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
450 5th Street, N.W.
Washington, D.C. 20530
(202) 305-0033
Kimberly.R.Stephens@usdoj.gov

BREON PEACE
United States Attorney

MICHAEL BLUME Digitally signed by MICHAEL BLUME Date: 2023.12.08 14:22:09 -05'00'

MICHAEL S. BLUME
Assistant United States Attorney
Eastern District of New York
271 Cadman Plaza East
Brooklyn, NY 11201
Michael.Blume@usdoj.gov
718-254-6479

OF COUNSEL:

MARK RAZA
Chief Counsel

SHANNON M. SINGLETON
Acting Deputy Chief Counsel, Litigation

ROSELLE N. OBERSTEIN
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-348-3011
roselle.oberstein@fda.hhs.gov